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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,545	01/23/2004	William C. Olson	2048/57906-E/JPW/MAF	7548

7590 07/26/2006

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,545	OLSON ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/16/04;1/11/05*. 8/29/05 & 7/3/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, filed on July 3, 2006. Applicant cancelled claims 1-108 and added new claims 109-140. Applicant elected Group II, drawn to a composition of previously pending claims 99-108, which corresponds to that of new claims 109-126. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). This restriction is made FINAL.

2. Since the composition of claims 109-126 is found free of the prior art, the method of using the composition of Group I, new claims 127-140, has rejoined with Group II. Accordingly, claims 109-140 are pending and are examined in the instant Office action.

Information Disclosure Statement

3. Initialed and dated copies of Applicant's IDS form 1449, filed on August 16, 2004, January 11, 2005, August 29, 2005 and July 3, 2006, are attached to the instant Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 110 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Since a monoclonal antibody can't only "consist of" CDRs, the claim 110 should say the CDR region of a monoclonal antibody consist of CDRs derived from the hybridoma cell line designated PA14 (ATCC Accession No. HB12610).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 109-140 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. The invention appears to employ novel biological materials, specifically a monoclonal antibody against β chemokine receptor. Since a monoclonal antibody against CCR5 is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. It is noted that Applicants have not deposited the hybridoma cells producing CCR5 antibodies and it is not apparent if the hybridoma cells are readily available to the public. The requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the hybridoma cells and

disclosure of a repeatable process to obtain the hybridoma cells in the specification.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become unviable.

Applicants is directed to 37 CFR § 1.807(b), which states:
(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
(1) The name and address of the depository;
(2) The name and address of the depositor;
(3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;

(5) The date of the viability test;
(6) The procedures used to obtain a sample if the test is not done by the depository; and
(7) A statement that the deposit is capable of reproduction.

Applicants is also directed to 37 CFR § 1.809(d) which states:
(d) For each deposit made pursuant to these regulations, the specification shall contain:
(1) The accession number for the deposit;
(2) The date of the deposit;
(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
(4) The name and address of the depository.

Applicants' attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(4), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information; however, Applicants is cautioned to avoid the entry of new matter into the specification by adding any other information.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may

be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 109-126 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 18, 31 and 74 of copending Application No. 10/371,483. It is noted that a notice of allowability of 10/371,483 has been mailed to Applicant on May 16, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the same product.

11. The instant claims 109-126 are drawn to a composition that comprises a monoclonal antibody designated as PA14 (ATCC Accession No. HB-12610) or a fragment or derivative with the same CDRs, wherein antibody or fragment of such antibody is humanized, wherein the humanized antibody comprises a framework from a human immunoglobulin.

12. The allowed claims of copending Application No. 10/371,483 are drawn to a humanized version of mouse anti-CCR5 antibody PA14 with same CDRs, designated as PRO 140 in the specification (see Figures 8-10, 10/371, 483). The subject maters of both sets of claims are not patentable distinct from each other. Therefore, the instant claims 109-126 are anticipated by allowed claims 1-5, 18, 31 and 74 of copending Application No. 10/371,483.

13. Claims 127-140 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 19-21 of U.S. Patent No. 7,060,273.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass same process using the same products.

14. The instant claims 127-140 are drawn to a method of treating a subject infected with HIV-1 which comprises administering to the subject an effective dose of the composition that comprises a monoclonal antibody or a fragment of such antibody binds to the same epitope as antibody PA14 produced by a hybridoma cell line designated PA14 (ATCC Accession No. HB-12610) and carrier, wherein antibody or fragment of such antibody is humanized, wherein the humanized antibody comprises a framework from a human immunoglobulin, wherein the antibody or fragment thereof is administered in a pharmaceutically acceptable carrier, wherein the dose of the antibody or fragment thereof is 0.1 to 100,000 mg/kg body weight of the subject, wherein the dose is administered by a route selected from the group consisting of oral, rectal, intra-vaginal, topic, nasal, ophthalmic and parenteral routes of administration, wherein the parenteral route comprises subcutaneous, intramuscular, intravenous or intra-sternal administration, wherein multiple doses are administered to the subject.

15. Claims 1-13 and 19-21 of U.S. Patent No. 7,060,273 are drawn to a method of reducing HIV-1 viral load in an HIV-1 infected subject which comprises administering to the subject solely post-infection an effective viral load-reducing amount of an agent which comprises a CDR domain of an anit-CCR5 antibody, which agent is monoclonal antibody PA14 (ATCC Accession No. HB-12610) or a fragment or derivative with the same CDRs, wherein the antibody is PA14 (ATCC Accession No. HB-12610), wherein the effective amount of the antibody is between 0.1 mg and 100 mg per kg body weight of the subject, wherein the antibody is administered intravenously, subcutaneously, intramuscularly, intraperitoneally, orally or topically, wherein the

subject is a human being and the antibody is a human antibody, wherein the subject is a human being and the antibody is a humanized antibody. 12. Since the method of 7,060,273 clearly encompasses the instant method of treating HIV infected patient using same product, the instant method of treating a subject infected with HIV-1 using a monoclonal antibody against CCR5 is anticipated by claims 1-13 and 19-21 of U.S. Patent No. 7,060,273.

Remarks

16. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.
7/21/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER